

Trovagene Reports Fourth Quarter and Year End 2016 Financial Results

Announces restructuring program to support its expansion into precision cancer therapeutics

Mar 15, 2017

SAN DIEGO, March 15, 2017 [/PRNewswire/](#) -- Trovagene, Inc. (NASDAQ: TROV), a precision medicine biotechnology company today reported financial results for the fourth quarter and year ended December 31, 2016. Additionally, Trovagene announced a restructuring program that will support the Company's expansion into precision cancer therapeutics.

In a separate press release today, Trovagene announced a license agreement with Nerviano Medical Sciences that grants Trovagene exclusive global development and commercialization rights to PCM-075, an oral, investigative drug and a highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK 1). A phase 1 safety study of PCM-075 was successfully completed in patients with advanced metastatic disease. Trovagene plans to develop PCM-075 initially in patients with acute myeloid leukemia (AML) and looks forward to initiating a clinical development plan this year.



"We are excited to announce the execution of our strategy to vertically integrate our ctDNA Precision Cancer Monitoring® (PCM) technology with precision cancer therapeutics by developing drugs where our deep understanding of tumor genomics may allow for effective targeting of appropriate cancer patients," said Bill Welch, CEO of Trovagene.

Trovagene estimates the restructuring program will reduce annual pre-tax expenses by approximately \$8.0 million per year (excluding one-time separation costs) through the reduction of approximately 30 personnel and expenses primarily linked to research, clinical studies and operations. Trovagene will maintain its CLIA/CAP-accredited laboratory for clinical services to pharmaceutical companies and for internal programs.

"This significant restructuring of the Company is necessary for Trovagene to be able to fully embrace its precision cancer therapeutic opportunities," said Bill Welch. "We believe today's announcement is in the best interest of all stakeholders as we look to build an industry leading precision medicine company."

Fourth Quarter 2016 Financial Results

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- Trovagene reported a net loss of \$8.5 million, or \$0.34 per diluted share, as compared to a net loss of \$10.2 million for the third quarter of 2016, and a net loss of \$7.4 million, or \$0.26 per diluted share, for the fourth quarter of 2015.
- Total operating expenses were approximately \$9.9 million in the fourth quarter, slightly down from \$10.0 million in the third quarter of 2016, and an increase from \$7.5 million in the fourth quarter of 2015.
- The net cash used in operating activities in the fourth quarter of 2016 was \$9.0 million, compared to \$7.0 million in the third quarter of 2016. The quarter-over-quarter increase can be attributed primarily to greater research and development costs associated with development of a multigene panel, a milestone payment to Boreal Genomics and certain non-recurring administration expenses.
- The weighted average of diluted shares of common stock outstanding used to calculate per share results was 30.7 million.
- As of December 31, 2016, Trovagene had cash, cash equivalents and short-term investments of approximately \$37.9 million.

Year End 2016 Financial Results

- Trovagene reported a net loss of \$39.2 million, or \$1.37 per diluted share, as compared to a net loss of \$27.5 million, or \$1.21 per diluted share, for the year ended December 31, 2015. The increase in net loss is primarily due to increased expenses related to research and development, sales and marketing, general and administrative, and restructuring charges versus the prior year.
- The net cash used in operating activities in 2016 was \$31.0 million, compared to \$22.1 million in 2015.

Conference Call Information

Trovagene will hold a conference call today at 5:00 p.m. Eastern Daylight Time (2:00 p.m. Pacific Daylight Time) to review its fourth quarter and year-end 2016 financial results. A live webcast of the Company's conference call will be available online at:

<https://www.webcaster4.com/Webcast/Page/1133/18788>

To access the conference call, please dial (888) 347-6081 (domestic), (412) 902-4285 (international), or (855) 669-9657 (Canada), conference ID# 10097532. To access the telephone replay of the call, dial (877) 344-7529 (domestic), (412) 317-0088 (international), or (855) 669-9658 (Canada), replay ID# 10097532. The replay will be available one hour after the conclusion of the call. The webcast and telephone replay will be archived on the Company's website following the conference at <http://trovagene.investorroom.com/events>.

About Trovagene, Inc.

Trovagene is a biotechnology company that leverages its proprietary Precision Cancer Monitoring® (PCM) technology in tumor genomics to effectively develop oncology therapeutics to target appropriate cancer patient populations. Trovagene has broad intellectual property and proprietary technology to measure circulating tumor DNA (ctDNA) in urine and blood to identify and quantify clinically actionable markers for predicting response to cancer therapies. Trovagene offers its PCM technology at its CLIA/CAP – accredited laboratory. Trovagene plans to continue to vertically integrate its PCM technology with precision cancer therapeutics by developing drugs. For more information, please visit www.trovagene.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Trovogene's expectations, strategy, plans or intentions. These forward-looking statements are based on Trovogene's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, our need for additional financing; our ability to continue as a going concern; clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; our ability to develop tests, kits and systems and the success of those products; regulatory, financial and business risks related to our international expansion and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that any of our technology or products will be utilized or prove to be commercially successful, or that Trovogene's strategy to design its liquid biopsy tests to report on clinically actionable cancer genes will ultimately be successful or result in better reimbursement outcomes. Additionally, there are no guarantees that future clinical trials will be completed or successful or that any precision medicine therapeutics will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Trovogene's Form 10-K for the year ended December 31, 2016, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Trovogene does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

(Financial Information to Follow)

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Trovogene, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except for per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Revenues:				
Royalties	\$ 50	\$ 52	\$ 258	\$ 275
Diagnostic services	17	3	86	14

Clinical research services	1	24	37	24
Total revenues	<u>68</u>	<u>79</u>	<u>381</u>	<u>313</u>
Costs and expenses:				
Cost of revenues	587	199	1,730	629
Research and development	3,785	3,166	15,007	10,594
Selling and marketing	2,396	1,935	11,523	6,444
General and administrative	2,292	2,164	11,476	7,920
Restructuring charges	790	-	790	-
Total operating expenses	<u>9,850</u>	<u>7,464</u>	<u>40,526</u>	<u>25,587</u>
Loss from operations	<u>(9,782)</u>	<u>(7,385)</u>	<u>(40,145)</u>	<u>(25,274)</u>
Net interest expense	(408)	(368)	(1,376)	(1,468)
Gain (loss) on change in fair value of derivative financial instruments-warrants	1,787	379	2,462	(726)
Other loss, net	(145)	(7)	(145)	(3)
Net loss	<u>\$ (8,548)</u>	<u>\$ (7,381)</u>	<u>\$ (39,204)</u>	<u>\$ (27,471)</u>
Preferred stock dividend	(6)	(6)	(24)	(24)
Net loss attributable to common stockholders	<u>\$ (8,554)</u>	<u>\$ (7,387)</u>	<u>\$ (39,228)</u>	<u>\$ (27,495)</u>
Net loss per common share - basic	<u>\$ (0.28)</u>	<u>\$ (0.25)</u>	<u>\$ (1.30)</u>	<u>\$ (1.05)</u>
Net loss per common share - diluted	<u>\$ (0.34)</u>	<u>\$ (0.26)</u>	<u>\$ (1.37)</u>	<u>\$ (1.21)</u>
Weighted average shares outstanding - basic	<u>30,639</u>	<u>29,723</u>	<u>30,175</u>	<u>26,202</u>
Weighted average shares outstanding - diluted	<u>30,712</u>	<u>30,157</u>	<u>30,281</u>	<u>26,452</u>

Trovagene, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	\$ 37,893	\$ 67,493
Accounts receivable	100	00

Accounts receivable	100	99
Prepaid expense and other assets	957	789
Total current assets	38,950	68,381
Property and equipment, net	3,827	2,691
Other assets	1,173	374
Total Assets	\$ 43,950	\$ 71,446

Liabilities and Stockholders' Equity

Current liabilities:		
Accounts payable	\$ 1,131	1,041
Accrued liabilities	4,021	1,904
Deferred rent	285	31
Current portion of long-term debt	2,360	5,226
Total current liabilities	7,797	8,202
Long-term debt, less current portion	14,176	11,246
Derivative financial instruments – warrants	835	3,297
Deferred rent, net of current portion	1,374	-
Total Liabilities	24,182	22,745
Stockholders' equity	19,768	48,701
Total liabilities and stockholders' equity	\$ 43,950	\$ 71,446

Trovagene, Inc. Condensed Consolidated Statements of Cash Flows (in thousands)

	Year Ended December 31,	
	2016	2015
Operating activities		
Net loss	\$ (39,204)	\$ (27,471)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,070	379
Stockbased compensation expense	7,504	3,946
Change in fair value of derivative financial instruments – warrants	(2,462)	726
Other non-cash items	964	439
Changes in operating assets and liabilities	1,088	(138)
Net cash used in operating activities	<u>(31,040)</u>	<u>(22,119)</u>
Investing activities:		
Capital expenditures, net	(823)	(2,233)
Net purchases of short-term investments	(24,010)	-
Net cash used in investing activities	<u>(24,833)</u>	<u>(2,233)</u>

Financing activities:		
Proceeds from sales of common stock, net of expenses	2,285	61,215
Proceeds from exercise of options	367	861
Proceeds from exercise of warrants	-	1,389
Net repayment (borrowings) of debt	(351)	1,086
Net cash provided by financing activities	<u>2,301</u>	<u>64,551</u>
Effect of exchange rate changes on cash and cash equivalents	(6)	-
Net change in cash and equivalents	(53,578)	40,199
Cash and cash equivalents—Beginning of period	67,493	27,294
Cash and cash equivalents—End of period	<u>\$ 13,915</u>	<u>\$ 67,493</u>

SOURCE Trovogene, Inc.

Additional assets available online:

 [Photos](#) (1)

<http://trovogene.investorroom.com/2017-03-15-Trovogene-Reports-Fourth-Quarter-and-Year-End-2016-Financial-Results>

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